PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORMS:

ZADIN 0,025 % NASAL DROPS
ZADIN 0,025 % NASAL SPRAY
ZADIN 0,05 % NASAL DROPS
ZADIN 0,05 % NASAL SPRAY

Read all of this leaflet carefully because it contains important information for you.

ZADIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use ZADIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ZADIN with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after five days.

1. WHAT ZADIN CONTAINS:

Active ingredients: Each 1 mℓ of ZADIN 0,025 % Nasal Drops and Nasal Spray solution contains 0,25 mg oxymetazoline hydrochloride.
Each 1 mℓ of ZADIN 0,05 % Nasal Drops and Nasal Spray solution contains 0,50 mg oxymetazoline hydrochloride.
Preservative: Benzalkonium chloride 0,0055 % *m/v.*
Inactive ingredients: Disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, sodium hydroxide, water for injection.

2. WHAT ZADIN IS USED FOR:

ZADIN is used for the temporary relief of nasal congestion in colds and influenza, hay fever, allergic rhinitis, other upper respiratory allergies, post-nasal drip and sinusitis.

3. BEFORE YOU USE ZADIN:

Do not use ZADIN:

- If you are allergic (hypersensitive) to oxymetazoline hydrochloride or to any of the ingredients in ZADIN (see "WHAT ZADIN CONTAINS").

- If you have inflammation in your nose or mucous membranes of your nostrils or have scabs in your nose.
- If you have had an operation to remove your pituitary gland.
- If you suffer from increased intraocular pressure (pressure inside the eye) (narrow-angle glaucoma).
- If you are taking (or have taken during the last 14 days) monoamine oxidase inhibitors (MAOIs) used in the treatment of Parkinson's disease and depression).
- If you have porphyria.
- If you have severe high blood pressure.
- If you have tumour on the adrenal gland called phaeochromocytoma**.**
- If you are pregnant or suspect that you are pregnant or if you are breastfeeding your baby (see "Pregnancy and breastfeeding").
- ZADIN 0,05 % is not recommended for use in children under 6 years of age.
- ZADIN 0,025 % is not recommended for use in children under 2 years of age.
- If you have acute heart disease or congestive heart failure (wheezing, coughing or shortness of breath).

Take special care with ZADIN:

- If your symptoms continue for more than 5 days while using ZADIN consult your doctor immediately. Do not use ZADIN for longer than 5 days.
- Using ZADIN for a long period may lead to rebound congestion (abnormal swelling and enlargement of the nasal passages, which blocks the nasal airway completely and causes extreme discomfort). Please consult your doctor if symptoms persist.
- If you have any heart disorder or high blood pressure (hypertension).
- If you have an overactive thyroid gland.
- If you have diabetes (high blood sugar).
- If you are an elderly person.
- If you have an enlarged prostate gland (prostate hypertrophy).
- Do not share ZADIN with other people, as it may spread the infection.
- Use ZADIN with caution in children, as they may be especially sensitive to the effects and side effects.

Using ZADIN with food or drink:

ZADIN may be used with or without food.

Pregnancy and breastfeeding:

DO NOT use ZADIN if you are pregnant or suspect that you are pregnant.

DO NOT use ZADIN if you are breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using ZADIN.

Driving and using machinery:
ZADIN has no influence on the ability to drive and use machines.
Do not drive or use machinery until you are sure that ZADIN does not affect your ability to drive or use machinery.

Using other medicines with ZADIN:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not take the following medicines in combination with ZADIN:
- Monoamine oxidase inhibitors (MAOIs) used in the treatment of Parkinson's disease and depression – do not use ZADIN if you have taken MAOIs during the last 14 days.
- Maprotiline (medicine used in treatment of depression).
- Tricyclic antidepressants (such as clomipramine, imipramine and amitriptyline) used in the treatment of depression.
- Medicines used to increase the sensitivity of the heart muscle and to stabilise the rhythm of the heart. This includes medicines such as digoxin (a cardiac glycoside), amiodarone, disopyramide, propafenone, flecainide and beta-blockers.
- Thyroid hormones (used to treat thyroid gland disorders).
- Antihypertensive medicines such as alpha-methyldopa used to lower high blood pressure.
- Ergot alkaloids (used to treat migraines or very severe headaches).
- Oxytocin (used to induce labour in women having weak or no contractions).
- Before receiving inhalation anaesthesia, tell your doctor that you are using ZADIN.

4. HOW TO USE ZADIN:

ZADIN 0,025 % for children 2 to 6 years of age (with adult supervision):

***How to use ZADIN 0,025 % Nasal Drops*:**
- Tilt the child's head back (this will ensure that the drops will penetrate as deeply as possible).
- Instill 1 to 3 drops into each nostril, not more often than every 10 to 12 hours.
- Ask the child to sniff in at the same time. (It will be easier to do so if the child is lying down on a bed).
- Move the child's head forward toward his/her knees for a few seconds, and then turn to the upright position.
- Do not use more than twice in 1 day.

- Wipe the tip of the dropper clean after each use.

How to use ZADIN 0,025 % Nasal Spray:

- Place the tip of the nozzle in one nostril without completely blocking the nostril.
- Bend head slightly forward and spray 2 to 3 times while sniffing in at the same time, not more than every 10 to 12 hours.
- Do this again with the other nostril.
- Do not use more than twice in 1 day.
- Wipe the nozzle clean after each use.

Do not use more often than what is recommended for your child or for longer than 5 days.

ZADIN 0,05 % for adults and children over 6 years of age:

***How to use ZADIN 0,05 % Nasal Drops*:**

- Hold the head well back.
- Instill 1 to 2 drops into each nostril, not more than every 10 to 12 hours.
- Sniff in at the same time. (It will be easier to do so if you are laying down on a bed).
- Do not use more than twice in 1 day.
- Wipe the tip of the dropper clean after each use.

How to use ZADIN 0,05 % Nasal Spray:

- Place the tip of the nozzle in one nostril without completely blocking the nostril.
- Bend your head slightly forward and spray 1 to 2 times while sniffing in at the same time, not more than every 10 to 12 hours.
- Do this again with the other nostril.
- Do not use more than twice in 1 day.
- Wipe the nozzle clean after each use.

Do not use more often than what is recommended for you or for longer than 5 days.

If you have any questions about the proper dose of ZADIN, ask your pharmacist or doctor.

If you use more ZADIN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

After administration of excessive doses pupil widening, nausea, abnormal blue discolouration of the skin and mucous membranes, fever, spasms, fast or slow heartbeat, irregular heartbeat, heart attack, high blood pressure, breathlessness, which may be very severe and usually worsens on lying down (oedema of the lungs), difficulty in breathing, psychic disturbance, drowsiness, lowering of the body temperature, low blood pressure, absence of breathing and loss of consciousness may occur.
Take this leaflet and the remaining product with you, so that the doctor knows what you have taken.

If you forget to use your ZADIN:
Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and use ZADIN at the next regular scheduled time. **Do not take a double dose to make up for the missed dose**.

5. POSSIBLE SIDE EFFECTS:

ZADIN may cause side effects.
Not all side effects reported for ZADIN are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while using ZADIN, please consult your doctor, pharmacist or other health care professional for advice.

Stop using ZADIN and find emergency medical help if you have any of these signs of an allergic reaction:

- Hives, difficulty breathing; swelling of your face, lips, tongue, or throat.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZADIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
Less frequent side effect:

- fast, irregular or pounding heartbeat.

Frequency not known:

- chest pain (anginal pain).

These are all serious side effects. You may need urgent medical attention.

Consult your healthcare professional if any of the following side effects continue or are bothersome:
Frequent side effects:

- dryness and a burning sensation in the nose.

- Sneezing.

Less frequent side effects:

- Headache,
- nervousness, anxiety, trembling,
- difficulty falling asleep,
- restlessness, irritability,
- nausea,
- flushing,
- skin rash, itching,
- worsening of the original congestion (rebound congestion), bleeding from the nose,
- high blood pressure,
- fast heart beat (tachycardia), fast or irregular heart beat (palpitations),
- drowsiness, sedation,
- fatigue,
- seeing, feeling or hearing things that are not there (which may occur mainly in children),
- convulsions (especially in children),
- absence of breathing in young infants and neonates.

Frequency not known:

- blurred vision,
- dizziness or lightheadedness,
- weakness,
- confusion,
- fear,
- pain,
- low blood pressure,
- increased nasal discharge,
- vomiting,
- reduced appetite,
- thirst,
- increased sweating,
- unusual paleness,
- goose bumps (piloerection),
- difficult or painful urination,
- retention of urine,

- increased saliva flow,
- cold extremities,
- fainting.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF ZADIN:

- Store at or below 25 °C.
- Do not remove from outer carton until required for use.
- Keep the container tightly closed when not in use.
- Discard this product if the solution changes colour.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF ZADIN:

ZADIN 0,025 % and ZADIN 0,05 % Nasal Spray:

White plastic bottle (HDPE) with a mechanical spraying device. Nasal spray pump consisting of a nasal actuator with white screw closure/protection cap and housing with basic pump system. Each bottle contains 10 mℓ of solution. Each carton contains 1 bottle.

ZADIN 0,025 % and ZADIN 0,05 % Nasal Drops:

White plastic bottle with a screw cap (both a mixture of LDPE and HDPE) and dropper (HDPE), containing 10 mℓ of solution. Each carton contains 1 bottle.

8. IDENTIFICATION OF ZADIN:

Zadin 0,025 % Nasal Drops and Nasal Spray: Colourless, clear solution.
Zadin 0,05 % Nasal Drops and Nasal Spray: Colourless, clear solution.

9. REGISTRATION NUMBERS

Zadin 0,025 % Nasal Drops: 44/16.1/0751
Zadin 0,025 % Nasal Spray: 44/16.1/0749
Zadin 0,05 % Nasal Drops: 44/16.1/0752
Zadin 0,05 % Nasal Spray: 44/16.1/0750

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd[1]
72 Steel Road,
Spartan
Kempton Park
1619
011 929 9000

[1] Company Reg. No.: 1990/001979/07

11. DATE OF PUBLICATION:

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